

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
COLUMBIA DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

ex rel. JON VITALE,

Relator,

v.

MIMEDX GROUP, INC.,

Defendant.

CA No. 3:17-cv-00166-RBH

**HIPAA QUALIFIED PROTECTIVE  
ORDER**

1. In accordance with the requirements of the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, as amended (see Pub. L. 104-191, 110 Stat. 1936; Pub. L. 111-5, 123 Stat. 115) (“HIPAA”), specifically 45 C.F.R. §§ 164.512(e)(1)(ii)(B) and 164.512(e)(1)(v), the Court hereby enters this Qualified Protective Order, as that term is defined in HIPAA.

2. The current parties (and their attorneys) and any future parties (and their attorneys) to the above-captioned action are hereby authorized to receive, subpoena and transmit “protected health information” (“PHI”) pertaining to MiMedx products, to the extent that such information is otherwise discoverable and not objectionable, subject to all conditions outlined herein pursuant to 45 C.F.R. § 164.512(e).

3. For the purposes of this Order, PHI shall have the same scope and definition as set forth in 45 C.F.R. § 160.103. Without limiting the generality of the foregoing, PHI refers to individually identifiable health information, including demographic information, collected from an individual, that: (1) is created or received by a health care provider, health plan, employer, or

health care clearinghouse; and (2) relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual, and (i) that identifies the individual, or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual. *See* 45 C.F.R. § 160.103.

4. This Order is not itself an authorization to obtain records. However, this Order does authorize “covered entities” and “business associates” (as defined by 45 C.F.R. § 160.103) to disclose PHI sought pursuant to discovery processes, to the attorneys for the parties now of record in this litigation or who may become of record in the future.

5. The parties and their attorneys shall be permitted to use and disclose PHI produced in this action solely for purposes of prosecuting or defending this action, including any appeals of this case. Permitted disclosures may be made in this litigation to: the receiving party, its officers, directors, employees and agents, counsel and their supporting personnel, including but not limited to paralegals, legal secretaries, data entry clerks, legal clerks and private document processing services, expert witnesses or consultants retained by the receiving party or its counsel, the Court and its staff, authors of or addressees or persons copied on any document designated as Confidential, court reporters and employees of court reporters engaged by counsel for a party to transcribe or videotape testimony in connection with this action, and/or other witnesses who may be called to testify at deposition or hearing/trial by the receiving party. The recipients of PHI pertaining to MiMedx products shall maintain it as confidential and are prohibited from using or disclosing it for any purpose other than in this litigation.

6. Furthermore, any witness who is not an officer, director, or employee of any of the parties to this litigation, any expert, consultant, or employee of any such expert or consultant, or

an employee of a third-party contractor providing document processing services, who is to be provided or shown PHI in the course of this litigation, must first receive a copy of this Order and execute a copy of the Declaration attached hereto as **Exhibit A**.

7. Except as otherwise provided in this paragraph, within 60 days after this proceeding ends, each party shall destroy all originals and copies of all PHI received from the other party, in whole or in part, in its possession, custody, or control. Upon written request, a party shall certify that it has complied with this paragraph. This paragraph, however, does not require the destruction of a working set of pleadings, orders, motions, or briefs for counsels' files.

8. Any party to this litigation and any third-party who is covered by this Order, who produces or discloses any document or thing that contains PHI, including, without limitation, any information, document, thing, interrogatory, answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: "CONFIDENTIAL—PROTECTED HEALTH INFORMATION."

9. Nothing contained in this Order authorizes counsel to obtain medical records or information through means other than formal discovery requests, subpoenas, depositions, patient authorizations or attorney-client communications. Moreover, the parties may seek additional protection from the disclosure and use of any documents and information for which they believe this Order does not provide adequate protection or with respect to documents and information which they believe are not subject to disclosure pursuant to applicable statutes, rules, regulations or other applicable law.

IT IS SO ORDERED.

August 6, 2019  
Florence, South Carolina

s/R. Bryan Harwell  
R. Bryan Harwell  
Chief United States District Judge

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**DECLARATION**

This is to certify that the undersigned has read and is fully familiar with the provisions of the HIPAA Qualified Protective Order (“Order”) entered on \_\_\_\_\_ in the above captioned action. As a condition precedent to my receipt and examination of Protected Health Information disclosed pursuant to the Order, or my obtaining any information derived from Protected Health Information, I hereby agree that the Order shall be deemed to be directed to and shall, include me, and that I shall be bound by, observe, and comply with the provisions of the Order. I further agree that I shall be subject to applicable enforcement and jurisdiction for any violation or attempted violation of the provisions of the Order. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

\_\_\_\_\_ Name (Signature)

\_\_\_\_\_ Name (Printed)

Dated: \_\_\_\_\_